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VACCINE INFORMATION STATEMENTS (VIS) SEGMENT of Immunization Update 2006, August 10, 2006.

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Risk and benefit communication between the provider and the person receiving the vaccine is essential. The cornerstone of immunization patient education is the Vaccine Information Statement, or VIS. Every healthcare provider, public or private, who administers a vaccine covered by the National Childhood Vaccine Injury Act is required by law to provide a copy of the most current VIS with EACH DOSE of vaccine administered. Not only the first dose, but EVERY dose. In addition, CDC encourages healthcare providers to use all available VISs, whether the National Childhood Vaccine Injury Act covers the vaccine or not. It is just good practice. Healthcare providers should also encourage the patient or their representative to take the VIS home. This is important because the VIS contains information that may be needed later, including the recommended schedule for that vaccine, information concerning what to look for and do after the vaccination, and what to do in the unlikely event of a severe reaction.

Healthcare providers are not required by Federal law to obtain the signature of the patient or their representative acknowledging receipt of the VIS. The VISs are not designed as informed consent documents. While the federal government does not require informed consent for vaccinations, some states or organizations may require a signature. You should consult your agency or state immunization program to determine if there are any specific informed consent requirements. Documentation that the VIS was given is required. Healthcare providers must note in each patient's permanent medical record or in a permanent office log or file, the date printed on the VIS and the date the VIS is given to the vaccine recipient, or their legal representative. Every VIS is dated. The date is always located in the corner of the second page of the document, and sometimes on the first page as well. This is the date that must be recorded in the patient's chart. VISs change periodically. Paying attention to this date also helps to ensure that your office always has the most current version of each VIS.

Speaking of most current versions, this graphic lists Vaccine Information Statements that are new or revised since our last Immunization Update broadcast in July 2005. There is a new

statement for TDAP that includes information for both adolescents and adults, and a new rotavirus vaccine statement. VISs that have been revised since last year include hepatitis A, influenza – both TIV and LAIV, meningococcal conjugate, and rabies vaccines. There are several new VISs currently being developed, including human papillomavirus and zoster vaccines. The varicella statement is also being revised to reflect the new two dose recommendation we discussed earlier. We have received many inquiries about VISs for newly licensed vaccines, such as HPV and zoster.

There seems to be a perception among some providers that since VISs are required by law for some vaccines that they cannot give ANY vaccine without a VIS. This is not true. Development of a VIS for a new vaccine, such as HPV, takes months. Providers should not withhold a vaccine just because a VIS is not yet available. You can provide the patient with the package insert, a fact sheet of your own design, or any other material that is available to inform patients about vaccine benefits and risks until the VIS is available. All English language Vaccine Information Statements are available from the National Immunization Program and state immunization programs. You will also find audio versions of the VISs on the NIP website. VISs are available in more than 25 languages on the Immunization Action Coalition website. We will have a link to all the Vaccine Information Statements on the broadcast updates and resources website.

To access the most accurate and relevant health information that affects you, your family and your community, please visit [www.cdc.gov](http://www.cdc.gov)